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| EXAMINER |
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BRUSCA, JOHN S

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| ART UNIT | PAPER NUMBER |
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1631

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| NOTIFICATION DATE | DELIVERY MODE |
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01/05/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@kilpatricktownsend.com
ipefiling@kilpatricktownsend.com
jlhice@kilpatrick.foundationip.com

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/765,291 | Applicant(s) GRAY ET AL. | |
| | Examiner JOHN S. BRUSCA | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 127,128,130-134,136-142 and 146-155 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 127,128,130,131,137 and 148 is/are rejected.
- 8) ☒ Claim(s) 132-134, 136, 138-147, and 149-155 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of the Claims

1. Claims 127, 128, 130-134, 136-142, and 146-155 are pending.

Claims 127, 128, 130, 131, 137, and 148 are rejected.

Claims 132-134, 136, 138-147, and 149-155 are objected to.

Drawings

2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Color drawings are referred to on pages 27-33 regarding figures 2A, 2B, 3, 5, 10, and 12. The applicants have not filed three sets of color drawings or the required petition, nor does the specification comprise the required statement noted above. The applicants should

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either delete the references to color in the drawings or amendment application file to conform with the requirements for color drawings.

Claim Objections

3. The objection to claim 137 in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

Claim Rejections - 35 USC § 103

4. The rejection of claims 127, 128, 130-134, 136, 139-141, 148, and 149 under 35 U.S.C. 103(a) as being unpatentable over Bartram et al. in view of Hopman et al. in view of Hariharan et al. in view of Shtivelman et al. in view of Lawrence et al. in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

5. The rejection of claims 127, 132-134, 136-138, 146, and 147 under 35 U.S.C. 103(a) as being unpatentable over Bartram et al. in view of Hopman et al. in view of Hariharan et al. in view of Shtivelman et al. in view of Lawrence et al. as applied to claims 127, 128, 130-134, 136, 139-141, 148, and 149 above, and further in view of Ribeiro et al. in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

6. The rejection of claims 127, 132, and 142 under 35 U.S.C. 103(a) as being unpatentable over Bartram et al. in view of Hopman et al. in view of Hariharan et al. in view of Shtivelman et al. in view of Lawrence et al. as applied to claims 127, 128, 130-134, 136,

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139-141, 148, and 149 above, and further in view of Selden et al. in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

7. The rejection of claims 127, 128, 148, 151, 152, and 154 under 35 U.S.C. 103(a) as being unpatentable over Bartram et al. in view of Hopman et al. in view of Hariharan et al. in view of Shtivelman et al. in view of Lawrence et al. as applied to claims 127, 128, 130-134, 136, 139-141, 148, and 149 above, and further in view of Lau et al. as evidenced by Westbrook (U.S. Patent No. 6,576,421) in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011..

8. The rejection of claims 127, 128, 148, 150, 153, and 155 under 35 U.S.C. 103(a) as being unpatentable over Bartram et al. in view of Hopman et al. in view of Hariharan et al. in view of Shtivelman et al. in view of Lawrence et al. as applied to claims 127, 128, 130-134, 136, 139-141, 148, and 149 above, and further in view of Frischauf et al. in view of Westbrook (U.S. Patent No. 6,576,421) in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011..

Double Patenting

9. The warning concerning duplicate claims 127, 128, and 148 in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

10. The rejection of claims 127, 128, 130-134, 136-142, 146-148, and 150-155 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 7, 8, 11-16, 19, 21, 22, 24, and 26-36 of U.S. Patent No. 6,576,421 in the Office

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action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

11. The rejection of claim 137 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,576,421 in view of Bartram et al. in view of Ribeiro et al. in the Office action mailed 05 May 2011 is withdrawn in view of the amendment received 07 November 2011.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 127, 128, 130, 131, and 148 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 11 and 14 of U.S. Patent No. 6,280,929. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matter of U.S. Patent No. 6,280,929 is a method of using the probes of the instant claims further limited to be a species of probe that is at least 50 kb in length and it would be obvious to make the probes required by the method of using the probes.

14. Claim 137 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 11, and 14 of U.S. Patent No. 6,280,929 in view of Bartram et al. in view of Ribeiro et al.

The claimed subject matter of claim 137 is a set of two probes for BCR and ABL genes with distinguishable labels that detect translocation breakpoints of a t(9;22)(q34;q11) translocation.

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Claims 4, 5, 11, and 14 of U.S. Patent No. 6,280,929 show a method of using two distinguishable fluorescently labeled probes for BCR and ABL genes.

Claims 4, 5, 11, and 14 of U.S. Patent No. 6,280,929 do not show probes that detect a t(9;22)(q34;q11) translocation.

Bartram et al. shows that patients with chronic myelocytic leukemia generally have a Philadelphia chromosome featuring rearranged ABL and BCR sequences.

Ribeiro et al. shows on page 948 that a Philadelphia chromosome has a t(9;22)(q34;q11) translocation. Ribeiro et al. shows on page 948 that the Philadelphia chromosome is considered to be a marker of CLL. Ribeiro et al. shows in the abstract and Table 1 18 patients that have both the Philadelphia chromosome and ALL.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make probes for analyzing chromosomes with a t(9;22)(q34;q11) translocation because Claims 4, 5, 11, and 14 of U.S. Patent No. 6,280,929 show a method of using two distinguishable fluorescently labeled probes for BCR and ABL genes and because Bartram et al. shows that patients with leukemia generally have a Philadelphia chromosome featuring rearranged ABL and BCR sequences and because Ribeiro et al. shows that the Philadelphia chromosome has a t(9;22)(q34;q11) translocation that correlates with CLL. It would have been further obvious to make probes for analyzing ABL-BCR junctions in cells from ALL patients because Ribeiro et al. also shows that some ALL patients have the Philadelphia chromosome.

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15. Applicant's arguments filed 03 March 2011 have been fully considered but they are not persuasive. The applicants state that the claims of U.S. Patent Nos. 6,280,929 are patentably distinct from the instant claimed subject matter because the issued patents claim a method and the instant claims are to a product. However a method of using a product is not distinct from the product unless the product can be used in a materially different process or the method can practiced with a materially different product (see MPEP 806.05(h)). Neither situation applies to the instant claims relative to the patents because the methods of the patents require use of the instant claimed products and the instant claimed products are limited to be useful for hybridization to their target in cytogenetic analysis, which is the process claimed in the patents. The instant application was not filed in response to a restriction requirement relative to the patents and application cited as references under double patenting and therefore there is no bar for double patenting over the cited references.

Allowable Subject Matter

16. Claims 132-134, 136, 138-147, and 149-155 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN BRUSCA whose telephone number is (571)272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/

Primary Examiner, Art Unit 1631

jsb